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Loper Bright and Materiality Under the False Claims Act

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The U.S. Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, which ended the decades-old doctrine of "*Chevron* deference," has opened new doors for litigants grappling with complex regulatory regimes. This is no less true in False Claims Act (FCA) litigation, where a defendant's liability often turns on the proper interpretation, effect, or applicability of agency regulations.

Background on *Loper Bright*

Before *Loper Bright*, when a statute was silent or ambiguous on a particular issue, courts had to "defer to the agency if it had offered 'a permissible construction of the statute,'" even if the court disagreed with the agency's construction. *Loper Bright* reversed this precedent, reaffirming the judiciary's duty to "police the outer statutory boundaries of [agency] delegations" by ensuring that agencies do not exceed their statutory authority.

Loper Bright thus presents a novel issue for FCA cases premised on regulatory violations. In the past, courts presiding over such cases "could simply defer to an agency's interpretation of a statute without too much handwringing over the province of the court versus the expertise of an agency."[i] Now, in the wake of *Loper Bright*, courts must ensure that the "regulatory scheme is consistent with the power given by Congress and the statute as it was signed into law."[ii]

FCA defendants have naturally begun to use *Loper Bright* as a tool to challenge the government's or a relator's theory of liability. So far, these challenges have focused on the FCA's "falsity" and "scienter" elements.[iii] But another element of the FCA—its "materiality" element—may prove to be an equally fertile ground for *Loper Bright* challenges.

Materiality under the FCA

Among its other prohibitions, the FCA imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government."

In 2016, the Supreme Court's decision in *Universal Health Services v. United States ex rel. Escobar* clarified the FCA's materiality element, holding that "statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment." "What matters," the court explained, "is not the label the government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the government's payment decision." The court emphasized that this standard "is demanding" and that it is not enough for relators or the government to identify "garden-variety breaches of contract or regulatory violations." Rather, they must show that the compliance with the underlying regulation was "so central" to the governmental program that the government "would not have paid the claims had it known of these violations."

How *Loper Bright* could affect this analysis

After *Loper Bright*, there is greater room for debate over which regulations can properly be considered material to the government's payment decisions. No doubt, "substantive" or "legislative rules"—i.e. rules having the force and effect of law[iv]—have a stronger claim to materiality (though the rule's substantive status alone would be insufficient to establish materiality under *Escobar*). The analysis is trickier, however, when it comes to "interpretive rules"—i.e. housekeeping rules which merely advise the public of the agency's interpretation of the statutes and rules it administers. In fact, it is unclear to what extent these rules can ever meet the materiality standard.

To illustrate, the Supreme Court has held in other contexts, such as its 2019 decision in *Kisor v. Wilkie*, that interpretive rules can "never form the basis for an enforcement action" because they do not "impose any legally binding requirements on private parties." Yet treating an interpretive rule as "material" for FCA purposes accomplishes a similar result to an enforcement action, as "the interpretive rule ends up having the 'force and effect of law' without ever paying the procedural cost." This result would be especially improper in cases where the agency that promulgated the rule lacked the power to make substantive rules in the first place.[v]

To be sure, cases predating both *Escobar* and *Loper Bright* held that violations of interpretive rules could form the basis for "imposing FCA liability, and even criminal false claims liability."[vi] But, by and large, the Courts of Appeals at that time had not settled on whether or when interpretive rules were entitled the *Chevron* deference.[vii] And, regardless, the judiciary's "obligation under *Loper*

Bright is different."[viii] As *Loper Bright* made clear, instead of blindly deferring to any agency interpretation, courts now "must respect" an agency's statutory authority "while ensuring that the agency acts within it." There does not appear to be any good reason why this "solemn duty" should apply less forcefully to—as *Escobar* characterized it—the FCA's "rigorous materiality requirement" than it does to every other statutory standard. Against this backdrop, *Loper Bright* arguably affords FCA defendants another basis on which to say that a given regulation is not material to the government's payment decisions.

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[i] *United States ex rel. Kyer v. Thomas Health Sys., Inc.*, NO. 2:20-cv-00732, 2024 WL 4165082, at *1 (S.D. W. Va. Sept. 12, 2024).

[ii] *Id.*

[iii] See, e.g., *United States ex rel. Sheldon v. Forest Labs, LLC*, No. ELH-14-2535, 2024 WL 3555116, at *32-33 (relying on *Loper Bright* to reject relator's falsity argument but finding *Loper Bright* inapplicable to the issue of scienter).

[iv] *Azar v. Allina Health Servs.*, 587 U.S. 566, 573 (2019).

[v] See, e.g., N*ew York v. U.S. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 527 (S.D.N.Y. 2019) (invalidating substantive rule because it could not "be justified based on [the agency's] authority under housekeeping statutes"); see also *Ryan LLC v. FTC*, --- F.Supp.3d ----, 2024 WL 3297524, at *10 (N.D. Tex. July 3, 2024) (finding that the FTC's power was limited to interpretive rulemaking and concluding that it "exceeded its statutory authority in promulgating" substantive rules).

[vi] *In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, 123 F. Supp. 3d 584, 608 n.14 (D.N.J. 2015) (quoting *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 351 (D. Conn. 2004)).

[vii] See, e.g., *Estate of Landers v. Leavitt*, 545 F.3d 98, 106 (2d Cir. 2008) (commenting that "nonlegislative rules are not per se ineligible for *Chevron* deference"); *Swallows Holding, Ltd. v. C.I.R.*, 515 F.3d 162, 169 n.9 (3d Cir. 2008) ("This Court has extended *Chevron* deference to interpretive rules in the past.").

[viii] *Kyer*, 2024 WL 4165082, at *1.